

## CLINICAL ETHICS

## HIV exceptionalism, CD4+ cell testing, and conscientious subversion

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In recent years, many states in the United States have passed legislation requiring laboratories to report the names of patients with low CD4 cell counts to their state Departments of Health. This name reporting is an integral part of the growing number of "HIV Reporting and Partner Notification Laws" which have emerged in response to recently revised guidelines suggested by the National Centers for Disease Control (CDC). Name reporting for patients with low CD4 cell counts allows for a more accurate tracking of the natural history of HIV disease. However, given that this test is now considered to be an "indicator" of HIV, should it be subject to the same strict consent required for HIV testing? While the CDC has recommended that each state develop its own consent requirements for CD4 cell testing, most states have continued to rely on the presumed consent standards for CD4 cell testing that were in place before the passage of name reporting statutes. This allows physicians who treat patients who refuse HIV testing to order a CD4 cell blood analysis to gather information that is indicative of their patient's HIV status. This paper examines the ethical and legal issues associated with the practice of "conscientious subversion" as it arises when clinicians use CD4 cell counts as a surrogate for HIV testing.

would make them vulnerable to discrimination and stigmatisation should they test positive.<sup>1–5</sup> This has led state governments to enact statutes that mandate strict informed consent requirements for HIV testing. These strict consent requirements distinguish HIV testing from other blood tests that are obtained with the presumed consent of the patient. They form part of what has come to be called "HIV exceptionalism".

HIV exceptionalism may be in its final stages. Many have argued for an end to it.<sup>1–11</sup> Indeed, as one writer explains, "as AIDS has become less threatening, the claims of those who argued that the exceptional threat would require exceptional policies have begun to lose their force".<sup>7</sup> In addition, the availability of more advanced antiretroviral therapies has made it possible to treat effectively those with HIV infection, thereby increasing the importance of early identification and tracking. These developments establish a strong case for moving beyond HIV exceptionalism and treating HIV antibody tests like other blood tests. Nonetheless, the strict consent requirements for HIV testing continue to be in place in almost all states and will, in all likelihood, continue to be so for some time.<sup>1</sup> These requirements have been justified by the important need to safeguard the privacy interests of those with this disease. However, given the importance of HIV testing for the proper care of infected individuals, some clinicians may think that it is appropriate, in effect, to circumvent the consent requirements if they can do so without violating the law. This can be accomplished by gathering information about the patient to serve as a surrogate marker for the disease, such as ordering blood tests to determine the patient's CD4+ cell count or viral load.<sup>12–13</sup>

There has been much discussion in the medical literature on the reliability of this information as an indicator of HIV,<sup>14–19</sup> but surprisingly little attention has been paid to the ethical issues that surround the practice of gathering such information as a surrogate for HIV testing.<sup>12–20–22</sup> These issues need to be explored if physicians are to understand fully the nature of their duties of privacy and confidentiality toward their patients.

## LEGAL REQUIREMENTS FOR CD4+ TESTING

Understanding the nature and limits of these duties is all the more pressing now that many states have passed legislation requiring laboratories to report the names of patients with low CD4+ cell counts to their state departments of public health (see chart 1). The name reporting

HIV testing and counselling are a crucial part of public health efforts to respond effectively to AIDS and other HIV related diseases. Information gained from testing is vital in enabling healthcare professionals to counsel HIV positive individuals to avoid risky behaviours and to access the healthcare services they need to manage their disease. However, according to public health experts, a substantial number of patients who are HIV positive are untested and have no knowledge of their status.<sup>1–3</sup> This puts those who care for them in a difficult position. When clinicians are unaware of their patient's HIV status, they may not be able to recommend and administer appropriate therapy.

The reasons why so many patients who are infected with HIV remain untested are numerous and complex,<sup>1–3–4</sup> but one reason stands out as particularly important in shaping healthcare policy. Many individuals at high risk for contracting HIV have expressed fear that testing

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of patients with low CD4+ cell counts is an integral part of the growing number of "HIV Reporting and Partner Notification Laws". These laws have emerged in response to the recently revised guidelines suggested by the National Centers for Disease Control (CDC).<sup>23-28</sup> They have been motivated by three basic concerns: (1) to enable more accurate tracking of HIV/AIDS infection; (2) to protect third parties and the public at large from communicable disease; and (3) to facilitate early treatment and improve the long term prognosis of HIV positive patients identified through screening.

The specific requirements of these laws vary from state to state. For example, some states, such as New York and Colorado, require clinical laboratories to report the names of those patients with reactive HIV antibody tests, HIV nucleic acid detection tests, and CD4 lymphocyte counts of less than 500 to the state Department of Health.<sup>9 20 29</sup> Other states stipulate slightly different requirements (see table 1). For example, Washington State requires name reporting of "tests indicative of HIV" such as Western blot assays, p24 antigen tests, viral culture tests, and HIV nucleic acid tests, as well as those tests considered to be "indicative of AIDS" such as CD4+ T lymphocytes less than 200 or 14%.<sup>30</sup>

Name reporting for patients with low CD4+ cell counts allows for more accurate tracking of the natural history of HIV disease.<sup>10</sup> However, given that this test is now considered to be an indicator of HIV, should it be subject to the same standard of strict consent required for HIV testing? The CDC has recommended that each state develop its own consent requirements for CD4+ cell testing.<sup>28</sup> For the most part, states have simply relied on the presumed consent standards for CD4+ testing that were in place before the passage of name reporting statutes (see table 1). According to these standards, physicians may presume consent for CD4+ testing when they deem it to be necessary. This allows physicians who treat patients who refuse HIV testing to order a CD4+ blood analysis to gather information that is indicative of the patient's HIV status. But although this option is legally permissible, the question remains whether it is ethically permissible?

## A CLINICAL CASE

To frame the discussion, consider an actual case discussed in a major medical journal.<sup>13</sup> Although this case took place in a New York City hospital, the issues it raises are not parochial. They should be of concern to all physicians who treat HIV infected patients and who are subject to laws that require

**Table 2** Representative sample of state laws concerning reporting of tests "indicative of HIV"

State	P24 antigen	Polymerase chain reaction (PCR)	Positive viral load	HIV nucleic acid tests
California	X	X	X	
Colorado	X	X	X	X
Florida	X	X*		
Maryland				
New York	X	X	X	
New Mexico				
Oregon				
Pennsylvania	X	X		
Washington	X		X	X

\*When used for confirmatory purposes.

CD4+ reporting, but do not mandate strict consent for CD4+ testing. The commentary on the case skilfully outlined the diagnostic procedures the physician undertook to identify the patient's HIV infection. However, while the commentary briefly alluded to the ethical issues raised in the case, it did not extensively discuss them. Nor have these issues received adequate attention elsewhere.<sup>20-22 31</sup>

A 35 year old male was admitted to a New York City hospital with a 10 day history of high fever and one day history of nausea, vomiting, and mild abdominal pain in the right upper quadrant. The patient appeared healthy, with no pallor, jaundice, or stigmata of liver insufficiency. He had a white cell count of 7600 per cubic millimetre, with 73% granulocytes, 24% lymphocytes, 2% monocytes, and 1% eosinophils. Suspecting viral hepatitis as a possible cause of his fever, the physician ordered tests for hepatitis antigens. No hepatitis B surface or e antigens were detected; but the tests revealed IgG antibodies to hepatitis B core antigen. An abdominal ultrasonogram revealed mild splenomegaly and a CT scan showed mild hepatosplenomegaly with a homogeneous parenchymal appearance. The physician noted that the presence of hepatitis B antibodies in combination with the splenomegaly and normocytic anaemia was consistent with HIV infection. With this in mind, he asked the patient to consent to HIV testing. The patient refused. The physician continued to suspect that the patient was HIV infected. He re-examined the patient thoroughly and then ordered an analysis of the patient's blood which revealed a CD4+ cell count of 592 cells per cubic millimetre and a CD8+ cell count of 843 cells per cubic millimetre, with a ratio of CD4:CD8 ratio of 0.7. Equipped with these findings, the physician

**Table 1** Representative sample of state laws concerning CD4+ cell reporting

State	Informed consent for HIV testing*	Informed consent for CD4+ cell testing	Report HIV/CD4+ cell results by name	Report HIV/CD4+ cell results by unique identifier	% of CD4+ cell count reportable by law on patients 13 years or older
California	Required by law	Not required by law		X	All diagnosed or suspected cases of AIDS as defined by the CDC†
Colorado	Required by law	Not required by law	X		CD4 Cell counts <500/mm or CD4%, 29%
Florida	Required by law	Not required by law	X		All diagnosed or suspected cases of AIDS as defined by the CDC*
Maryland	Required by law	Not required by law		X	CD4 cell counts ≤200 or 14% of total lymphocytes
New York	Required by law	Not required by law	X		CD4 cell counts <500/mm or CD4%, 29%
New Mexico	Required by law	Not required by law	X		CD4 cell counts ≤200 or 14% of total lymphocytes
Oregon	Required by law	Not required by law	X		CD4 cell counts ≤200 or 14% of total lymphocytes
Pennsylvania	Required by law	Not required by law	X		CD4 cell counts ≤200 or 14% of total lymphocytes
Washington	Required by law	Not required by law	X		CD4 cell counts ≤200 or 14% of total lymphocytes

\*"HIV testing" refers to either HIV-1 ELISA or Western blot test.

†The CDC has broadened its definition of AIDS to include CD4 cell counts equal to or less than 200/μl or 14% and/or the presence of any one of 26 opportunistic infections.

asked the patient to reconsider consenting to HIV testing. The patient, however, continued to refuse. A whole body scan disclosed marked uptake of gallium citrate in a large, poorly defined area of the left buttock. These findings prompted the physician to consider that the patient might have a deeply seated soft tissue tumour. He reasoned that if HIV infection were present, then the unusual location of gallium uptake could represent a non-Hodgkin's lymphoma. At this point the patient admitted that he had been seropositive for HIV for eight years. He demanded that this information be kept secret without notation in the medical record or notification of the nursing staff or his family. A transcutaneous biopsy was performed with CT guidance, which revealed a high grade diffuse immunoblastic lymphoma.

## ANALYSIS

The treating physician's conduct in this case was a model of careful diagnostic investigation. His sustained efforts to identify the cause of the patient's high fever led him to suspect that the patient was HIV positive. Moreover, it is clear from the case that the treating physician violated no law. He did not infringe the patient's legal right to refuse HIV testing. His decision to order a blood analysis of the patient's CD4+ cell levels did not violate any consent requirement. As mentioned above, under New York state law the requirement for such tests is presumed consent, not the stringent informed consent required for HIV testing. Finally, in defense of his conduct, the physician could claim that he needed to acquire the information about the patient's CD4+ cell count to enable him to pursue his diagnostic investigation.

Still, in his efforts to determine whether the patient was HIV positive, the physician appears to have circumvented the consent requirement that prevented him from obtaining this information. He used the CD4+ blood analysis as a surrogate marker for HIV. Equipped with this information, he then attempted to persuade the patient to consent to HIV testing to confirm the diagnosis of HIV infection.

Is this conduct ethically permissible? Is it ever ethically permissible for physicians to circumvent HIV consent requirements if they have a good medical reason for doing so? An argument can be made that physicians have a duty not only to adhere to the law concerning HIV testing, but also a duty to respect the moral spirit behind the law. On this view, if the law is justified because it safeguards the patient's right not to know about his condition and to keep others from knowing about it, then it would be wrong for a physician to circumvent the law because doing so would violate the rights and interests that the law attempts to protect. In the case under discussion, the physician took aggressive steps to help him determine whether the patient had HIV and thereby potentially violated the patient's right to privacy with respect to his condition.

For these reasons, many will conclude that the physician acted wrongly in the above case. They will think that if the physician wished to determine the patient's CD4+ cell count, then he should have explicitly sought the patient's consent to do so after carefully explaining to him that this information could be an (imperfect) indicator of HIV infection. However, this analysis of the case assumes that the legal requirement of strict consent for HIV testing is justified. There is reason to doubt that it is. The consent requirements for HIV testing imposed by states may be largely motivated by political factors rather than by sound medical and public health considerations.<sup>1-10</sup> For reasons already mentioned, a growing segment of the medical and public health community have called for an end to HIV exceptionalism and a number of physicians have explicitly called for a liberalisation of the strict consent requirements for HIV testing.<sup>1-10-11</sup> Given this, we should take seriously the possibility that the consent

requirement the physician circumvented in the case was not justified or that the physician himself did not consider the law mandating strict consent for HIV testing to be reasonable.

If the law was not reasonable, and if the physician believed that it was not reasonable, this might be relevant to the ethical analysis of the case. Clinicians should not break the law (unless perhaps if the law is grossly unjust), but it does not follow from this that they should do their best to comply with the moral spirit of laws that they believe to be unreasonable. The physician in the case we are considering may have reasonably believed that for good medical reasons HIV should be treated like other communicable diseases.<sup>1-10-11-26</sup> Furthermore, he may have believed that if it had been so treated, then he would have been able to test the patient for HIV without first securing his explicit consent. He then would have been able to recommend early treatment for the disease and encourage the patient to discuss his condition with his spouse and others who might be at risk of contracting the disease.

This possibility raises an important, and insufficiently discussed, issue in clinical medical ethics, one that we can refer to as *conscientious subversion*. This issue is related to, but different from, the issues of conscientious objection and civil disobedience. A physician might refuse to participate in some medical practice, such as performing an abortion, that he deems to be immoral. This would be an instance of conscientious objection.<sup>32-33</sup> Alternatively, a physician might openly break a law to call public attention to some perceived injustice in the healthcare setting, such as when a physician openly breaks a law against physician assisted suicide as a way of urging reform in the law. This would be an instance of civil disobedience.<sup>34-36</sup> Conscientious subversion differs from both of these in that the physician does not break a law and he does not refrain from participating in a medical practice of which he disapproves. Instead, he acts to circumvent the purposes for which the law exists. And he does so because he believes that this is in the best interests of his patient or is justified by public health considerations.

The physician in the above case may have engaged in such an act of conscientious subversion. He may have thought that his duty to pursue the best medical interests of his patient was in conflict with the law that mandates strict consent requirements on HIV testing. And he may have believed that he had an ethical duty to subvert the law by ordering a CD4+ blood analysis as a means of gathering information about the patient's HIV status.

It is tempting to respond that clinicians should never attempt to subvert the law. They should always strive to comply with both the letter and the spirit of the laws that regulate their practice. But the possibility of justified conscientious subversion should not be dismissed so quickly. There are clear circumstances in which a morally decent clinician would be required to circumvent the law. To take an extreme example: if the South African legislature in 1980 passed a law that prohibited physicians from prescribing penicillin to non-white patients—and if breaking the law was not an option in the circumstances—then morally decent physicians would do all that they could to circumvent this law. For example, they would prescribe other antibiotics to their non-white patients that would have similar therapeutic effects as penicillin. This is, to be sure, an extreme example; but it reveals an important point. It is a mistake to think that physicians should never engage in conscientious subversion no matter what law is in question. If one were to believe the physician in the case we are considering acted wrongly, then one would need to explain why his action was not justified conscientious subversion.



## FURTHER ISSUES

A key principle of "preventive ethics" is that physicians should not put themselves in situations in which they face intractable ethical dilemmas. This helps to explain why physicians should not conscientiously subvert the consent requirements for HIV testing. It is true that sometimes physicians may not intend to circumvent these requirements. The discovery that their patient is, in all likelihood, HIV positive may be an incidental finding of their diagnostic investigation, not one that they consciously aimed at. Nevertheless, irrespective of their intentions, if physicians order diagnostic tests from which they can infer their patient's HIV status (such as CD4+ blood analysis), then they will need to decide whether to withhold this information from their patients.<sup>13</sup> If they withhold this information, then their patients may not be persuaded to consent to an HIV test to confirm their condition. This, in turn, would prevent their physicians from recommending and administering the therapy they need. In addition, once physicians strongly suspect that their patients are HIV positive they may have an ethical duty to report this information to those who are at risk of contracting the disease.

However, if physicians disclose this information to their patients, they will have violated their patients' right not to be informed about their HIV status and their right not to have this information disclosed. In effect, they will have run roughshod over their patients' expressed wishes not to be informed about their condition. Either way it appears that physicians who put themselves in this situation must act wrongly.

Of course, in the case we have been considering, the physician believed that he needed to order the CD4+ blood analysis to pursue his diagnostic investigation into the possible causes of the patient's condition. But if doing so places him in the ethical dilemma we have just described, then he should consider first seeking the patient's consent for the CD4+ blood analysis. And he should do so only after explaining to the patient that this analysis could potentially reveal information about the patient that would be indicative of HIV infection.

But what if the patient had then refused to consent to the CD4+ blood test? If this happened, then the physician would seriously need to consider refusing to treat the patient and transferring his care to another physician. Before doing so, he should carefully explain to the patient that he has a duty to do his best to identify the cause of the patient's condition and that, in his judgement, he cannot discharge this duty without proceeding with the CD4+ blood analysis. In this way, the physician could both respect the privacy interests of his patient as well as remain true to his conviction that he must be permitted to continue his diagnostic investigation if he is to recommend and administer appropriate therapy.

Compelling as these considerations may be, they pale in significance compared with the risks to patient confidentiality that conscientious subversion of HIV consent requirements engender. The case under discussion occurred before the passage of the New York state law that mandates name reporting of patients with very low CD4+ counts. But, as mentioned above, some version of these laws is now on the books in many states.<sup>26-27</sup> This creates additional ethical problems for physicians who would order a CD4+ blood analysis for patients who refuse HIV testing. Patients whose blood analysis reveals very low CD4+ counts will be reported to their state's department of public health. In the case we are considering, the patient's CD4+ count was 592 cells per cubic millilitre. This is sufficiently high to avoid reportability. However, the physician in the case could not have known this before ordering the test. Had the patient's CD4+ count been lower than 500 cells per cubic millilitre then the lab would

have been required to report it to the New York State Department of Public Health. This would have triggered an investigation to determine the source of the low CD4+ cell count, which has the potential to compromise further the interests of those patients who wish to keep their HIV status confidential.

Importantly, state laws do allow some opportunities to avoid the reportability of patients with low CD4+ counts. For example, under many state laws laboratories need not report the names of patients with low CD4+ counts if the patients are subjects of research or their physicians indicate that they suffer from cancer related illness. To take advantage of these exceptions, however, the patient must be legitimately enrolled in a research protocol or his physician must sincerely believe that the patient's illness is not HIV related. A physician, like the one discussed in the case we have been considering, who orders a CD4+ blood test and who strongly suspects that his patient is HIV infected, will face the difficult choice of either falsely representing the patient's condition to the lab or placing at risk his patient's interest in keeping his HIV status confidential.

Certainly, many clinicians who treat patients with HIV may be unaware of the existence of state laws that require labs to report the names of patients with low CD4+ counts. If so, they may believe that the information gathered from the CD4+ blood analysis can be strictly limited to those involved in the care of the patient. This underscores the importance of the clinician's duty to be informed about changes in the law that might bear on the privacy and confidentiality interests of his or her patients. Since more and more states are passing mandatory reporting and partner notification laws for those with HIV,<sup>26-27</sup> physicians need to be aware of these changes and the difficulties they create for protecting patient confidentiality. This is particularly true for those physicians who might consider engaging in conscientious subversion with respect to the consent requirements for HIV testing.

## CONCLUSION

The case we have considered in this paper is not atypical.<sup>12</sup> With recent advances in the treatment of AIDS, clinicians understand the importance of early identification of HIV related illness. They have a duty to gather information that will help them form and confirm a diagnostic hypothesis concerning their patient's condition. Without this information, they will be unable to recommend appropriate therapy. This duty, however, can conflict with the duty to respect the privacy and confidentiality interests of patients with HIV. For those patients who refuse HIV testing, clinicians understandably are tempted to pursue diagnostic interventions that may indirectly indicate HIV infection, such as ordering CD4+ blood tests.

Before states began passing reporting and partner notification laws for those who test positive for HIV (and for those whose blood analysis reveals very low CD4+ counts), many clinicians may have believed that they could finesse this conflict. Any information they discovered that might indicate HIV infection could be kept strictly to themselves. Whether or not this was ever an ethically satisfactory solution, it clearly is no longer a viable option. Today clinicians who treat patients with HIV must attempt to temper their aggressive efforts to identify the cause of their patients' condition with a greater awareness of the potential dangers such efforts pose to the privacy and confidentiality interests of these patients.

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